

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

August 2016

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male

M1

M2

M3

M4

M5

Female

F1

F2

F3

F4

F5

the data would be shown as:

Male			Female		
M1	M2	M3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 3
 Report Date: 08/09/2016

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	052000603	03/14/07	727	50(3)	20(644)	584.8	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
Female							
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene

Version: Aug2016
Contract/Lab: All Laboratories
Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 08/09/2016

Male					Female				
#All Organs: Benign Tumors									
Overall Incidence	Total	27/50 (54%)	30/50 (60%)	SD 4.24%	Total	40/50 (80%)	39/50 (78%)	SD 1.41%	
		57/100 (57%)	Mean 57%			79/100 (79%)	Mean 79%		
#All Organs: Malignant Tumors									
Overall Incidence	Total	12/50 (24%)	12/50 (24%)	SD 0%	Total	14/50 (28%)	11/50 (22%)	SD 4.24%	
		24/100 (24%)	Mean 24%			25/100 (25%)	Mean 25%		
#All Organs: Malignant and Benign Tumors									
Overall Incidence	Total	33/50 (66%)	37/50 (74%)	SD 5.66%	Total	46/50 (92%)	41/50 (82%)	SD 7.07%	
		70/100 (70%)	Mean 70%			87/100 (87%)	Mean 87%		
#All Organs: Hemangioma									
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	SD 1.41%	Total	0/50 (0%)	0/50 (0%)	SD 0%	
		1/100 (1%)	Mean 1%			0/100 (0%)	Mean 0%		
#All Organs: Hemangiosarcoma									
Overall Incidence	Total	1/50 (2%)	0/50 (0%)	SD 1.41%	Total	1/50 (2%)	0/50 (0%)	SD 1.41%	
		1/100 (1%)	Mean 1%			1/100 (1%)	Mean 1%		
#All Organs: Hemangiosarcoma or Hemangioma									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	SD 0%	Total	1/50 (2%)	0/50 (0%)	SD 1.41%	
		2/100 (2%)	Mean 2%			1/100 (1%)	Mean 1%		

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 08/09/2016

Male						Female						
#All Organs: Histiocytic Sarcoma												
Overall Incidence	Total	0/50	(0%)	0/50	(0%)	SD 0%	Total	1/50	(2%)	0/50	(0%)	SD 1.41%
		0/100	(0%)	Mean 0%	Mean 1%							
.....												
#All Organs: Leukemia: Granulocytic												
Overall Incidence	Total	0/50	(0%)	1/50	(2%)	SD 1.41%	Total	0/50	(0%)	0/50	(0%)	SD 0%
		1/100	(1%)	Mean 1%	Mean 0%							
.....												
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated												
Overall Incidence	Total	0/50	(0%)	3/50	(6%)	SD 4.24%	Total	0/50	(0%)	0/50	(0%)	SD 0%
		3/100	(3%)	Mean 3%	Mean 0%							
.....												
#All Organs: Mesothelioma: Benign, Malignant, NOS												
Overall Incidence	Total	1/50	(2%)	1/50	(2%)	SD 0%	Total	0/50	(0%)	0/50	(0%)	SD 0%
		2/100	(2%)	Mean 2%	Mean 0%							
.....												
#All Organs: Mesothelioma: Malignant												
Overall Incidence	Total	1/50	(2%)	1/50	(2%)	SD 0%	Total	0/50	(0%)	0/50	(0%)	SD 0%
		2/100	(2%)	Mean 2%	Mean 0%							
.....												
*Adrenal Cortex: Adenoma												
Overall Incidence	Total	0/50	(0%)	3/50	(6%)	SD 4.24%	Total	0/50	(0%)	0/50	(0%)	SD 0%
		3/100	(3%)	Mean 3%	Mean 0%							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male						Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma											
		0/50	(0%)	2/50	(4%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	2/100 (2%)		Mean 2%	SD 2.83%		Total	1/100 (1%)		Mean 1%	SD 1.41%
<hr/>											
*Brain: Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%		Total	1/100 (1%)		Mean 1%	SD 1.41%
<hr/>											
*Epididymis: Sarcoma											
		0/50	(0%)	1/50	(2%)						
Overall Incidence	Total	1/100 (1%)		Mean 1%	SD 1.41%						
<hr/>											
#Eye: Leiomyoma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100 (1%)		Mean 1%	SD 1.41%		Total	0/100 (0%)		Mean 0%	SD 0%
<hr/>											
*Heart: Schwannoma Malignant											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100 (1%)		Mean 1%	SD 1.41%		Total	0/100 (0%)		Mean 0%	SD 0%
<hr/>											
#Intestine Large: Colon/Rectum: Leiomyoma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100 (1%)		Mean 1%	SD 1.41%		Total	0/100 (0%)		Mean 0%	SD 0%

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male						Female						
#Intestine Small: Jejunum: Leiomyosarcoma												
Overall Incidence	Total	0/50 1/100 (1%)	(0%)	1/50 Mean 1%	(2%)	SD 1.41%	Total	0/50 0/100 (0%)	(0%)	0/50 Mean 0%	(0%)	SD 0%
#Intestine Small: Site Unspecified: Leiomyosarcoma												
Overall Incidence	Total	0/50 1/100 (1%)	(0%)	1/50 Mean 1%	(2%)	SD 1.41%	Total	0/50 0/100 (0%)	(0%)	0/50 Mean 0%	(0%)	SD 0%
*Islets, Pancreatic: Adenoma												
Overall Incidence	Total	2/50 10/100 (10%)	(4%)	8/50 Mean 10%	(16%)	SD 8.49%	Total	0/50 1/100 (1%)	(0%)	1/50 Mean 1%	(2%)	SD 1.41%
*Islets, Pancreatic: Carcinoma												
Overall Incidence	Total	0/50 0/100 (0%)	(0%)	0/50 Mean 0%	(0%)	SD 0%	Total	0/50 1/100 (1%)	(0%)	1/50 Mean 1%	(2%)	SD 1.41%
*Islets, Pancreatic: Carcinoma or Adenoma												
Overall Incidence	Total	2/50 10/100 (10%)	(4%)	8/50 Mean 10%	(16%)	SD 8.49%	Total	0/50 2/100 (2%)	(0%)	2/50 Mean 2%	(4%)	SD 2.83%
*Kidney: Renal Tubule: Adenoma												
Overall Incidence	Total	1/50 1/100 (1%)	(2%)	0/50 Mean 1%	(0%)	SD 1.41%	Total	0/50 1/100 (1%)	(0%)	1/50 Mean 1%	(2%)	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male										Female					
*Kidney: Renal Tubule: Carcinoma or Adenoma															
Overall Incidence	Total	1/100 (1%)	1/50 (2%)	Mean	0/50 (0%) 1%	SD	1.41%	Total	1/100 (1%)	0/50 (0%)	1/50 (2%)	Mean	0/50 (0%) 1%	SD	1.41%
*Liver: Hepatocellular Adenoma															
Overall Incidence	Total	1/100 (1%)	1/50 (2%)	Mean	0/50 (0%) 1%	SD	1.41%	Total	4/100 (4%)	2/50 (4%)	2/50 (4%)	Mean	4/100 (4%) 4%	SD	0%
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma															
Overall Incidence	Total	1/100 (1%)	1/50 (2%)	Mean	0/50 (0%) 1%	SD	1.41%	Total	4/100 (4%)	2/50 (4%)	2/50 (4%)	Mean	4/100 (4%) 4%	SD	0%
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma															
Overall Incidence	Total	1/100 (1%)	1/50 (2%)	Mean	0/50 (0%) 1%	SD	1.41%	Total	4/100 (4%)	2/50 (4%)	2/50 (4%)	Mean	4/100 (4%) 4%	SD	0%
*Lung: Alveolar/Bronchiolar Adenoma															
Overall Incidence	Total	0/99 (0%)	0/49 (0%)	Mean	0/50 (0%) 0%	SD	0%	Total	1/100 (1%)	1/50 (2%)	0/50 (0%)	Mean	1/100 (1%) 1%	SD	1.41%
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma															
Overall Incidence	Total	0/99 (0%)	0/49 (0%)	Mean	0/50 (0%) 0%	SD	0%	Total	1/100 (1%)	1/50 (2%)	0/50 (0%)	Mean	1/100 (1%) 1%	SD	1.41%

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male												Female			
*Lung: Sarcoma															
Overall Incidence	Total	0/49 0/99	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	Total	1/50 1/100	(2%) (1%)	0/50 Mean	(0%) 1%	SD	1.41%	
#Lymph Node, Mesenteric: Hemangiosarcoma															
Overall Incidence	Total	1/50 1/100	(2%) (1%)	0/50 Mean	(0%) 1%	SD	1.41%	Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	
#Mammary Gland: Adenoma															
Overall Incidence	Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	Total	3/50 7/100	(6%) (7%)	4/50 Mean	(8%) 7%	SD	1.41%	
#Mammary Gland: Carcinoma															
Overall Incidence	Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	Total	3/50 8/100	(6%) (8%)	5/50 Mean	(10%) 8%	SD	2.83%	
#Mammary Gland: Carcinoma or Adenoma															
Overall Incidence	Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	Total	6/50 15/100	(12%) (15%)	9/50 Mean	(18%) 15%	SD	4.24%	
#Mammary Gland: Fibroadenoma															
Overall Incidence	Total	1/50 3/100	(2%) (3%)	2/50 Mean	(4%) 3%	SD	1.41%	Total	29/50 49/100	(58%) (49%)	20/50 Mean	(40%) 49%	SD	12.73%	

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male										Female							
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma																	
		1/50	(2%)	2/50	(4%)						30/50	(60%)	23/50	(46%)			
Overall Incidence	Total	3/100	(3%)	Mean	3%	SD	1.41%				Total	53/100	(53%)	Mean	53%	SD	9.9%
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma																	
		1/50	(2%)	2/50	(4%)						32/50	(64%)	27/50	(54%)			
Overall Incidence	Total	3/100	(3%)	Mean	3%	SD	1.41%				Total	59/100	(59%)	Mean	59%	SD	7.07%
#Mammary Gland: Myoepithelioma																	
		0/50	(0%)	0/50	(0%)						1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	0/100	(0%)	Mean	0%	SD	0%				Total	1/100	(1%)	Mean	1%	SD	1.41%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma																	
		1/50	(2%)	0/50	(0%)						0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%				Total	0/100	(0%)	Mean	0%	SD	0%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma																	
		1/50	(2%)	0/50	(0%)						0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%				Total	0/100	(0%)	Mean	0%	SD	0%
#Oral Mucosa: Squamous Cell Carcinoma																	
		1/50	(2%)	0/50	(0%)						0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%				Total	0/100	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male										Female															
*Ovary: Granulosa Cell Tumor Benign																									
Overall Incidence										Total	0/50 3/100	(0%) (3%)	3/50 Mean 3%		(6%)	SD 4.24%									
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS																									
Overall Incidence										Total	0/50 3/100	(0%) (3%)	3/50 Mean 3%		(6%)	SD 4.24%									
*Ovary: Granulosa-Theca Tumor Benign																									
Overall Incidence										Total	1/50 1/100	(2%) (1%)	0/50 Mean 1%		(0%)	SD 1.41%									
*Ovary: Thecoma Benign																									
Overall Incidence										Total	0/50 1/100	(0%) (1%)	1/50 Mean 1%		(2%)	SD 1.41%									
*Ovary: Tubulostromal Carcinoma																									
Overall Incidence										Total	1/50 1/100	(2%) (1%)	0/50 Mean 1%		(0%)	SD 1.41%									
*Pancreas: Adenoma																									
Overall Incidence										Total	5/50 5/100	(10%) (5%)	0/50 Mean 5%		(0%)	SD 7.07%		Total	0/50 0/100	(0%) (0%)	0/50 Mean 0%		(0%)	SD 0%	

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male						Female						
*Pancreas: Carcinoma or Adenoma												
Overall Incidence	Total	5/50 (10%)	5/100 (5%)	0/50 (0%)	Mean 5%	SD 7.07%	Total	0/50 (0%)	0/100 (0%)	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma												
Overall Incidence	Total	5/50 (10%)	16/100 (16%)	11/50 (22%)	Mean 16%	SD 8.49%	Total	18/50 (36%)	36/100 (36%)	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
Overall Incidence	Total	5/50 (10%)	16/100 (16%)	11/50 (22%)	Mean 16%	SD 8.49%	Total	18/50 (36%)	36/100 (36%)	18/50 (36%)	Mean 36%	SD 0%
*Salivary Glands: Schwannoma Malignant												
Overall Incidence	Total	1/50 (2%)	1/100 (1%)	0/50 (0%)	Mean 1%	SD 1.41%	Total	0/50 (0%)	0/100 (0%)	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma												
Overall Incidence	Total	0/50 (0%)	0/100 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	1/100 (1%)	1/50 (2%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Sarcoma												
Overall Incidence	Total	0/50 (0%)	0/100 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	1/100 (1%)	0/50 (0%)	Mean 1%	SD 1.41%

#: Denominator is number of animals necropsied

Male										Female												
#Skin:																						
Basal Cell Carcinoma																						
		1/50		(2%)		0/50		(0%)				0/50		(0%)		1/50		(2%)				
Overall Incidence	Total	1/100		(1%)		Mean		1%		SD		1.41%		Total	1/100		(1%)		Mean		1%	
#Skin:																						
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)																						
		1/50		(2%)		0/50		(0%)				0/50		(0%)		1/50		(2%)				
Overall Incidence	Total	1/100		(1%)		Mean		1%		SD		1.41%		Total	1/100		(1%)		Mean		1%	
#Skin:																						
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma																						
		1/50		(2%)		0/50		(0%)				0/50		(0%)		1/50		(2%)				
Overall Incidence	Total	1/100		(1%)		Mean		1%		SD		1.41%		Total	1/100		(1%)		Mean		1%	
#Skin:																						
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma																						
		6/50		(12%)		4/50		(8%)				0/50		(0%)		1/50		(2%)				
Overall Incidence	Total	10/100		(10%)		Mean		10%		SD		2.83%		Total	1/100		(1%)		Mean		1%	
#Skin:																						
Fibroma																						
		5/50		(10%)		0/50		(0%)				1/50		(2%)		0/50		(0%)				
Overall Incidence	Total	5/100		(5%)		Mean		5%		SD		7.07%		Total	1/100		(1%)		Mean		1%	
#Skin:																						
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma																						
		7/50		(14%)		1/50		(2%)				2/50		(4%)		0/50		(0%)				
Overall Incidence	Total	8/100		(8%)		Mean		8%		SD		8.49%		Total	2/100		(2%)		Mean		2%	

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

		Male				Female								
#Skin: Fibrosarcoma														
		1/50	(2%)	0/50	(0%)		1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma														
		2/50	(4%)	1/50	(2%)		1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	3/100	(3%)	Mean	3%	SD	1.41%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin: Fibrous Histiocytoma														
		1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	2/100	(2%)	Mean	2%	SD	0%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin: Hemangioma														
		0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin: Hemangiosarcoma														
		0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	0/100	(0%)	Mean	0%	SD	0%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin: Keratoacanthoma														
		4/50	(8%)	3/50	(6%)		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	7/100	(7%)	Mean	7%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 16
 Report Date: 08/09/2016

Male						Female								
#Skin:														
Lipoma														
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin:														
Neurofibrosarcoma or Schwannoma (malignant or NOS)														
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	0/100	(0%)	Mean	0%	SD	0%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)														
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	0/100	(0%)	Mean	0%	SD	0%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Schwannoma Malignant														
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	0/100	(0%)	Mean	0%	SD	0%	Total	1/100	(1%)	Mean	1%	SD	1.41%
.....														
#Skin:														
Squamous Cell Carcinoma														
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%
.....														
#Skin:														
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma														
		2/50	(4%)	0/50	(0%)			0/50	(0%)	1/50	(2%)			
Overall Incidence	Total	2/100	(2%)	Mean	2%	SD	2.83%	Total	1/100	(1%)	Mean	1%	SD	1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male										Female					
#Skin: Squamous Cell Papilloma															
		1/50	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	2/100 (2%)	Mean	2%	SD	0%	Total	0/100 (0%)	Mean	0%	SD	0%			
.....															
#Skin: Squamous Cell Papilloma or Papilloma															
		1/50	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	2/100 (2%)	Mean	2%	SD	0%	Total	0/100 (0%)	Mean	0%	SD	0%			
.....															
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma															
		5/50	(10%)	4/50	(8%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	9/100 (9%)	Mean	9%	SD	1.41%	Total	0/100 (0%)	Mean	0%	SD	0%			
.....															
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma															
		5/50	(10%)	4/50	(8%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	9/100 (9%)	Mean	9%	SD	1.41%	Total	0/100 (0%)	Mean	0%	SD	0%			
.....															
#Skin: Sebaceous Gland: Adenoma															
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/100 (1%)	Mean	1%	SD	1.41%	Total	0/100 (0%)	Mean	0%	SD	0%			
.....															
#Skin: Sebaceous Gland: Carcinoma or Adenoma															
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/100 (1%)	Mean	1%	SD	1.41%	Total	0/100 (0%)	Mean	0%	SD	0%			

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male										Female				
#Stomach, Forestomach: Squamous Cell Carcinoma														
		1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	1/100 (1%)		Mean 1%		SD 1.41%		Total	1/100 (1%)	Mean 1%		SD 1.41%		
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous														
		1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	1/100 (1%)		Mean 1%		SD 1.41%		Total	1/100 (1%)	Mean 1%		SD 1.41%		
*Testes: Adenoma														
		3/49	(6%)	0/50	(0%)									
Overall Incidence	Total	3/99 (3.03%)		Mean 3.06%		SD 4.33%								
*Thymus: Thymoma Benign														
		1/46	(2%)	0/48	(0%)			0/47	(0%)	0/50	(0%)			
Overall Incidence	Total	1/94 (1.06%)		Mean 1.09%		SD 1.54%		Total	0/97 (0%)	Mean 0%		SD 0%		
*Thymus: Thymoma: Benign, Malignant, NOS														
		1/46	(2%)	0/48	(0%)			0/47	(0%)	0/50	(0%)			
Overall Incidence	Total	1/94 (1.06%)		Mean 1.09%		SD 1.54%		Total	0/97 (0%)	Mean 0%		SD 0%		
*Thyroid Gland: C-Cell: Adenoma														
		13/50	(26%)	2/50	(4%)			11/49	(22%)	2/50	(4%)			
Overall Incidence	Total	15/100 (15%)		Mean 15%		SD 15.56%		Total	13/99 (13.13%)	Mean 13.22%		SD 13.05%		

#: Denominator is number of animals necropsied

Version: Aug2016
Contract/Lab: All Laboratories
Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 19
Report Date: 08/09/2016

Male										Female				
*Thyroid Gland: C-Cell: Carcinoma														
Overall Incidence	Total	0/50	(0%)	1/50	(2%)	SD	1.41%	Total	0/49	(0%)	0/50	(0%)	SD	0%
		1/100	(1%)	Mean	1%				0/99	(0%)	Mean	0%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma														
Overall Incidence	Total	13/50	(26%)	3/50	(6%)	SD	14.14%	Total	11/49	(22%)	2/50	(4%)	SD	13.05%
		16/100	(16%)	Mean	16%				13/99	(13.13%)	Mean	13.22%		
#Tooth: Odontoma														
Overall Incidence	Total	0/50	(0%)	1/50	(2%)	SD	1.41%	Total	0/50	(0%)	0/50	(0%)	SD	0%
		1/100	(1%)	Mean	1%				0/100	(0%)	Mean	0%		
#Uterus: Carcinoma														
Overall Incidence								Total	0/50	(0%)	1/50	(2%)	SD	1.41%
									1/100	(1%)	Mean	1%		
#Uterus: Polyp Stromal														
Overall Incidence								Total	10/50	(20%)	7/50	(14%)	SD	4.24%
									17/100	(17%)	Mean	17%		
#Uterus: Sarcoma Stromal														
Overall Incidence								Total	2/50	(4%)	0/50	(0%)	SD	2.83%
									2/100	(2%)	Mean	2%		

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Report Date: 08/09/2016

Male						Female					
#Uterus: Sarcoma Stromal or Polyp Stromal											
Overall Incidence						Total	12/50 19/100	(24%) (19%)	7/50 Mean	(14%) 19%	SD 7.07%
.....											
#Uterus: Squamous Cell Carcinoma											
Overall Incidence						Total	0/50 1/100	(0%) (1%)	1/50 Mean	(2%) 1%	SD 1.41%
.....											
#Vagina: Granular Cell Tumor Benign											
Overall Incidence						Total	0/50 1/100	(0%) (1%)	1/50 Mean	(2%) 1%	SD 1.41%
.....											
#Vagina: Polyp											
Overall Incidence						Total	1/50 1/100	(2%) (1%)	0/50 Mean	(0%) 1%	SD 1.41%
.....											
#Vagina: Schwannoma Malignant											
Overall Incidence						Total	1/50 2/100	(2%) (2%)	1/50 Mean	(2%) 2%	SD 0%
.....											
#Zymbal's Gland: Carcinoma											
Overall Incidence						Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
Contract/Lab: All Laboratories
Species: RATS
Strain: Harlan Sprague-Dawley
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Male												Female			
#Zymbal's Gland: Carcinoma or Adenoma															
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/100	(1%)	Mean	1%	SD	1.41%	Total	0/100	(0%)	Mean	0%	SD	0%	